



Our STN: BL 125771/0

MID-CYCLE COMMUNICATION

AGENDA

October 24, 2022

Bioverativ Therapeutics Inc.
Attention: Hei-Jen Sun, PhD
55 Corporate Drive
Bridgewater, NJ 08807

Dear Dr. Sun:

Attached is a copy of the agenda for your October 26, 2022, Mid-Cycle Communication Teleconference with CBER.

Please include a reference to STN BL 125771/0 in your future submissions related to the subject product.

If you have any questions, please contact Niloofar Kennedy at Niloofar.kennedy@fda.hhs.gov.

Sincerely,

Basil Golding, MD
Director
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Mid-Cycle Communication Teleconference Agenda

Application Type and Number: BLA 125771/0

Product Name: Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein

Proposed Indication for Use: Treatment of adults and children with Hemophilia A (congenital Factor VIII deficiency) for:
(1) Routine prophylaxis to reduce the frequency of bleeding episodes; (2) On-demand treatment and control of bleeding episodes; (3) Perioperative management of bleeding.

Applicant: Bioverativ Therapeutics Inc.

Meeting Date & Time: October 26, 2022 at 11:00 AM, ET

Committee Chair: Zuben Sauna, PhD

RPM: Niloofar Kennedy, MS

Agenda:

1. Any significant issues/major deficiencies identified by the Review Committee to date.
 - a. No significant issues/major deficiencies identified at this time.
2. Information regarding major safety concerns.
 - a. No major safety concerns have been identified to date.
3. Preliminary Review Committee thinking regarding risk management.
 - a. At this time, the review teams have not identified a need for a Risk Evaluation Mitigation Strategy (REMS).
4. Any information requests sent, and responses not received.
 - a. No outstanding information requests.
5. Any new information requests to be communicated.
 - a. As review continues, new information requests will be conveyed as warranted.
6. Proposed date(s) for the Late-Cycle Meeting and the Late-Cycle Meeting Materials:
 - a. Late Cycle Meeting is scheduled for December 19, 2022, from 10:00 AM-11 AM, ET.
 - b. Meeting materials will be provided by December 9, 2022.
7. Updates regarding plans for the AC meeting, if appropriate.

- a.** AC meeting is not anticipated.
- 8.** Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates.